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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/810,939	03/16/2001	Mary Capelli-Schellpfeffer	3066.1000-001	7242

757 7590 10/14/2004
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EXAMINER

GHALI, ISIS A D

ART UNIT PAPER NUMBER

1615

DATE MAILED: 10/14/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/810,939

Applicant(s)CAPELLI-SCHELLPFEFFER,
MARY**Examiner**

Isis Ghali

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 07/24/2004.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 80-108 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 80-108 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. §§ 119 and 120

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
* See the attached detailed Office action for a list of the certified copies not received.
- 13) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application) since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.
a) ☐ The translation of the foreign language provisional application has been received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121 since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ 6) ☐ Other: _____

DETAILED ACTION

The receipt is acknowledged of applicant's request for extension of time, amendment, and request under 1.114, all filed 07/24/2004.

Claims 1-79 have been cancelled. Claims 80-108 have been added and included in the prosecution.

Continued Examination Under 37 CFR 1.114

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 07/14/2004 has been entered.

Specification

2. The specification has not been checked to the extent necessary to determine the presence of all possible minor errors. Applicant's cooperation is requested in correcting any errors of which applicant may become aware in the specification.

3. The use of the trademark "AVOGEL" has been noted in this application. It should be accompanied by the generic terminology.

Although the use of trademarks is permissible in patent applications, the proprietary nature of the marks should be respected and every effort made to prevent their use in any manner which might adversely affect their validity as trademarks.

Claim Rejections - 35 USC § 112

4. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

5. Claims 80, 81, 83, 88-92, 94-100, and 106 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The claims are confusing because the generic claims 80 and 81 recite administration of a composition by one of: administration to the closed wound (which can be by injection), by injection or orally, while the dependent claims 89-91 and 98-99 recite the composition comprising thermal insulating materials consisting of gel, hydrogel or sponge that are used for topical formulations only that is not recited by the claims. Clarification is requested.

Regarding claim 81, the claim contains improper Markush language that renders the claim reads as the composition comprising one of each of: the cyclooxygenase inhibitors, NF-kB inhibitors, and prostaglandin E2 inhibitors. The proper Markush format to be followed in the claim should have the expression "selected from the group

consisting of", and only the last two members of the Markush group are separated by the connector operator "and" OR "or".

Regarding claims 89, 90, 98, 100, a broad range or limitation together with a narrow range or limitation that falls within the broad range or limitation (in the same claim) is considered indefinite, since the resulting claim does not clearly set forth the metes and bounds of the patent protection desired. The claims are rendered indefinite by raising a question or doubt introduced by the wide and narrow limitations because it is subject of more than one interpretation, and one interpretation would render the claim unpatentable over the prior art. In the present instance, the claims recite the broad recitation "thermal insulating material", and the claims also recite "gel", "hydrogel" and "sponge" which is the narrower statement of the range/limitation.

Claims 91, 99 and 106 contain the trademark/trade name "AVOGEL". Where a trademark or trade name is used in a claim as a limitation to identify or describe a particular material or product, the claim does not comply with the requirements of 35 U.S.C. 112, second paragraph. See *Ex parte Simpson*, 218 USPQ 1020 (Bd. App. 1982). The claim scope is uncertain since the trademark or trade name cannot be used properly to identify any particular material or product. A trademark or trade name is used to identify a source of goods, and not the goods themselves. Thus, a trademark or trade name does not identify or describe the goods associated with the trademark or trade name. In the present case, the trademark/trade name is used to identify/describe thermal insulating material and, accordingly, the identification/description is indefinite.

Claim Rejections - 35 USC § 102

6. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

7. Claims 80-90, 92-94, 98, 100 are rejected under 35 U.S.C. 102(b) as being anticipated by DE 27 07 537 ('537).

DE '537 disclosed formulations for treatment of keloids comprising salicylic acid in an amount of 1-3%. The formulations comprises gel and a substances that relieve skin irritation.

8. Claims 80-86 are rejected under 35 U.S.C. 102(b) as being anticipated by JP 08-268886 ('886).

JP '886 disclosed treatment and improvement of the skin diseases such as keloids by administering composition comprising aspirin or its salts in a carrier by external application, orally or by injection (abstract; paragraphs 001, 0013, 0014, 0017, 0021).

9. Claims 80-90, 92 are rejected under 35 U.S.C. 102(b) as being anticipated by JP 08-259465 ('465).

JP '465 disclosed external preparation for skin treatment of conditions such as keloid and hypertrophic scar. The composition comprises 1-60% of non-steroidal anti-inflammatory agents, such as indomethacin, ibuprofen, and flufenamic acid, in a carrier and a gel (abstract; paragraphs 0001, 0008, 0019, 0022).

10. Claims 80-86 are rejected under 35 U.S.C. 102(e) as being anticipated by US 6,652,856 ('856) with the effective filing date April 22, 1999.

US '856 disclosed method of treating fibrosis like dermal keloids and hypertrophic scar by applying topical or oral composition comprising sulfasalazine and a carrier (abstract; col.5, lines 66-67; col.6, lines 1, 15-17, 30-36; col.11, lines 54-66; col.12, lines 1-10, 28; col.14, lines 4-13).

11. Claims 80-88, 93, 94 are rejected under 35 U.S.C. 102(e) as being anticipated by US 6,521,271 ('271) with the effective filing date of August 16, 1999.

US '271 disclosed method of improving skin conditions such as scar by topical, oral or parenteral administration of a composition comprising 1-20% of salicylic acid and a carrier; and another antimicrobial agent or anti-inflammatory agent (abstract; col.3, lines 13-15, 35-37, 39-40; col.7, lines 15-23, 40; col.8, lines 19-21, 26, 30, 38-50).

Claim Rejections - 35 USC § 103

12. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

13. Claims 91, 95-97, 99, 101-108 are rejected under 35 U.S.C. 103(a) as being unpatentable over DE '537.

The teachings of DE '537 are discussed above, the reference however does not teach the hydrogel as the thermal insulating material, the amount of the non steroidal or the specific other active agent in the composition.

The art recognized the use of gel and anti-irritants in the composition comprising COX that is used to treat keloids, thus, the specific hydrogel material and the specific anti-irritants used by present invention do not impart patentability to the claims, absent evidence to the contrary. The amounts used by the present invention do not impart patentability to the claims, absent evidence to the contrary.

Thus, it would have been obvious to one having ordinary skill in the art at the time of the invention to provide the composition disclosed by DE '537 and select the specific thermal insulating materials and anti-irritants according to specific patient's need, and adjust the amounts according to the size and thickness of the scar, with

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reasonable expectation of having a composition comprising non-steroidal anti-inflammatory agent, anti-irritant, and a hydrogel that treat keloids with success.

14. Claims 91, 95-97, 99, 101-108 are rejected under 35 U.S.C. 103(a) as being unpatentable over DE '537 in view of US 5,552,162 ('162).

The teachings of DE '537 are discussed above, the reference however does not teach the hydrogel as the insulating material, the amount of the non steroidal or the specific other active agent in the composition.

The art recognized the use of anti-irritants in the composition comprising COX that is used to treat keloids, thus, the specific anti-irritants used by present invention do not impart patentability to the claims, absent evidence to the contrary. The amounts used by the present invention do not impart patentability to the claims, absent evidence to the contrary.

US '162 teaches a method for improving the size and appearance of the scar associated with keloid or hypertrophic wound healing disorder by covering the scar with thermal insulating material and active agent (abstract). The thermal insulating materials includes hydrogel and gel (col.9, lines 10-12, 27). The thermal insulating material elevates the surface temperature of the scar and consequently stimulates the collagenase activity and improves the size and the appearance of the scar (col.6, lines 1-32).

Thus, it would have been obvious to one having ordinary skill in the art at the time of the invention to provide the method for treating the scar by administering a

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composition comprising salicylic acid and gel as disclosed by DE '537, and replace the gel by thermal insulating hydrogel disclosed by US '162, motivated by the teaching of US '162 that the thermal insulating material elevates the surface temperature of the scar and consequently stimulates the collagenase activity and improves the size and the appearance of the scar as desired by the applicant, with reasonable expectation of having a composition comprising the salicylic acid, anti-irritant and hydrogel that improves the size and the appearance of the scar of the closed wound with success.

15. Claims 87-108 are rejected under 35 U.S.C. 103(a) as being unpatentable over JP '886 in view of US '162.

The teachings of JP '886 and US '162 are discussed above. JP '886 does not teach the thermal insulating material, the amount of the non-steroidals or the other active agents in the composition.

The specific other active ingredients used by present invention do not impart patentability to the claims, absent evidence to the contrary. The amounts used by the present invention are within skill in the art to determine, absent evidence to the contrary.

Thus, it would have been obvious to one having ordinary skill in the art at the time of the invention to provide the method for improving the keloid by administering a composition comprising aspirin as disclosed by JP '886, and add thermal insulating hydrogel disclosed by US '162, motivated by the teaching of US '162 that the thermal insulating material elevates the surface temperature of the scar and consequently stimulates the collagenase activity and improves the size and the appearance of the

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scar as desired by the applicant, with reasonable expectation of having a composition comprising the aspirin and hydrogel that improves the size and the appearance of the scar of the closed wound with success.

16. Claims 91, 93-108 are rejected under 35 U.S.C. 103(a) as being unpatentable over JP '465.

The teachings of JP '465 are discussed above, the reference however does not teach the hydrogel as the thermal insulating material, or the specific other active agents in the composition.

The specific hydrogel material and the specific additives and the specific thermal insulating materials used by present invention do not impart patentability to the claims, absent evidence to the contrary.

Thus, it would have been obvious to one having ordinary skill in the art at the time of the invention to provide the composition disclosed by JP '465 and select the specific thermal insulating materials and anti-irritants, with reasonable expectation of having a composition comprising non-steroidal anti-inflammatory agent, anti-irritant, and a hydrogel that treat keloids with success.

17. Claims 91, 93-108 are rejected under 35 U.S.C. 103(a) as being unpatentable over JP '465 in view of US '162.

The teachings of the references are discussed above. JP '465 does not teach the hydrogel as the thermal insulating material, or the specific other active agent in the composition.

The specific other actives used by present invention do not impart patentability to the claims and it is within the skill in the art to add any other additives or actives as needed, absent evidence to the contrary.

Thus, it would have been obvious to one having ordinary skill in the art at the time of the invention to provide the method for improving the keloid or hypertrophic scar by administering a composition comprising non-steroidal anti-inflammatory agent and gel as disclosed by JP '465, and replace the gel by thermal insulating hydrogel disclosed by US '162, motivated by the teaching of US '162 that the thermal insulating material elevates the surface temperature of the scar and consequently stimulates the collagenase activity and improves the size and the appearance of the scar as desired by the applicant, with reasonable expectation of having a composition comprising the aspirin and hydrogel that improves the size and the appearance of the scar of the closed wound with success.

18. Claims 87-108 are rejected under 35 U.S.C. 103(a) as being unpatentable over US '856 in view of US '162.

The teachings of the references are discussed above. However, US '856 does not teach the thermal insulating material, the amount of the non-steroidals or the other active agent in the composition.

The specific other active ingredients used by present invention do not impart patentability to the claims, absent evidence to the contrary. The amounts used by the present invention are within skill in the art to determine, absent evidence to the contrary.

Thus, it would have been obvious to one having ordinary skill in the art at the time of the invention to provide the method for improving the keloid and hypertrophic scar by administering a composition comprising sulfasalazine as disclosed by US '856, and add thermal insulating hydrogel disclosed by US '162, motivated by the teaching of US '162 that the thermal insulating material elevates the surface temperature of the scar and consequently stimulates the collagenase activity and improves the size and the appearance of the scar as desired by the applicant, with reasonable expectation of having a composition comprising the aspirin and hydrogel that improves the size and the appearance of the scar of the closed wound with success.

19. Claims 89-92, 95-108 are rejected under 35 U.S.C. 103(a) as being unpatentable over US '271 in view of US '162.

The teachings of the references are discussed above. US '271 does not teach the hydrogel as the thermal insulating material, or the specific other active agent in the composition.

The specific other actives used by present invention do not impart patentability to the claims and it is within the skill in the art to add any other additives or actives as needed, absent evidence to the contrary.

Thus, it would have been obvious to one having ordinary skill in the art at the time of the invention to provide the method for improving the scar by administering a composition comprising non-steroidal anti-inflammatory agent as disclosed by US '271, and add the thermal insulating hydrogel disclosed by US '162, motivated by the teaching of US '162 that the thermal insulating material elevates the surface temperature of the scar and consequently stimulates the collagenase activity and improves the size and the appearance of the scar as desired by the applicant, with reasonable expectation of having a composition comprising the aspirin and hydrogel that improves the size and the appearance of the scar of the closed wound with success.

Response to Arguments

20. Applicant's arguments filed 07/24/2004 have been fully considered but they are not persuasive.

Applicant traverses the rejection of the claims over DE '537 by arguing that the reference discloses a preparation which is suitable for local treatment or control of hypertrophic cicatrisation in can and the preparation treats "sebaceous accumulations, pustules, and papules as they may occur in acne vulgaris" as well as other disorders, which are associated with hyperplasia that has been brought about by infected sebaceous glands. The reference teaches a preparation containing salicylic acid that can be used as an "exfoliant," the mainstay treatment of acne. Thus, the reference teaches treating is a blocked pore and not a closed wound. Thus, while DE '537

teaches use of a preparation for removing cells, the present invention teaches a method of using a composition to promote growth of cells. Lee, U.S. Patent No. 5,552, 162 neither discloses nor suggests inhibiting cyclooxygenase activity, either directly or indirectly, to achieve improvement in the size or appearance of a closed wound.

In response to the above argument, the examiner position is that the DE reference is directed to treatment for "hypertrophic cicatrization of the skin" that is caused by acne. According to the "WEBESTER'S II Dictionary", the term "hypertrophic" is defined as "abnormal large size of organ or cell", and the term "cicatrization" is defined as "recently formed connective tissue on a healing wound, scar tissue". The applicant disclosed the closed wound as a scar. Thus, the teaching of the reference is directed to treatment of scar as claimed by applicant, and scar should grow on closed or healed wound and not on an open wound. The reference teaching is directed to treatment of scar, caused by acne, and reduce its size, and that what exactly desired by applicant, to improve the size of the scar and not to promote growth of the cells as applicant asserts.

US '162 is relied upon for teaching the thermal insulating material combined with medicaments to reduce the size of the scar, as desired by applicants.

21. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Isis Ghali whose telephone number is (571) 272-0595. The examiner can normally be reached on Monday-Thursday, 7:00 to 5:30.

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Thurman Page can be reached on (571) 272-0602. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Isis Ghali
Examiner
Art Unit 1615

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